

Stroke Center Designation TCD Stroke Workgroup Recommendations

Note: On December 2, 2008, the TCD Workgroup voted and approved the following criteria; as well, they voted that the criteria be passed on to the TCD Regulations Workgroup. A couple of items are still under discussion (see yellow highlighted text), and those items will be resolved by the Regulations Workgroup.

Edits made by the Stroke Education sub-group at the Jan. 6, 2009 meeting are indicated in red.

Level I Comprehensive Stroke Centers

- Requirements:
 - Meets the requirements specified in the Consensus Statement of Stroke on Comprehensive Stroke Centers. (Recommendations for comprehensive Stroke centers: a consensus statement from the Brain Attack Coalition. Stroke. 2005; 36(7):1597-616.
 - Meets the requirements specified for a Primary Stroke Center as specified by The Joint Commission.
 - Follows current Joint Commission Core Measures:
 - DVT prophylaxis
 - Discharged on antithrombotic therapy
 - Patients with A-Fibrillation receiving anticoagulation
 - Thrombolytic therapy administered
 - Antithrombotic therapy by end of hospital day 2
 - Discharged on cholesterol-reducing medication
 - Dysphagia screening
 - Stroke education
 - Smoking cessation education/advice/counseling
 - Assessed for rehabilitation
 - Follows the Brain Attack Coalition's benchmark treatment times:
 - Door to physician exam = 10 minutes
 - Door to Stroke Activation = 15 minutes
 - Door to CT Scan = 25 minutes
 - Door to CT Report = 45 minutes
 - Door to tPA = 60 minutes
 - Hospital and Administrative support
 - Transfer agreements in place to serve as Hub to care for complex cerebrovascular cases for lower level hospitals in the region
 - The institution has and maintains a stroke registry

- Medical Director—include 3 or more of the following:
 - Board certified neurologist or vascular neurosurgeon with a stroke fellowship, or neurocritical care fellowship, or vascular neurosurgery fellowship or equivalent experience
 - Board certified in vascular neurology or neurocritical care
 - Fellow of the Stroke Council of the AHA
 - Clinician who diagnoses and treats at least 50 patients with cerebrovascular disease annually or more than 50% of his/her time is dedicated to the care of cerebrovascular patients and/or research on cerebrovascular disease
 - Clinician with at least 10 peer-reviewed publications dealing with cerebrovascular disease
 - Clinician with at least 12 CME credits each year in areas directly related to cerebrovascular disease
- Neurologists and Neurosurgeons
 - Board certified/board eligible
 - Neurosurgical expertise shall be available 24/7, and response time in person or by phone within 5 minutes
 - There shall be personnel in-house (or be at the hospital within 20 minutes) who are capable of performing emergent neurosurgical procedures
 - Shall have expertise and experience in microsurgery for aneurysm clipping and surgical excision of AVM's
 - Written neurosurgical call schedules shall be available
 - The institution shall care for at least 30 SAH patients per year and shall accomplish at least 10 craniotomies per year for aneurysm clipping and at least 10 endovascular coilings of aneurysms
 - Each Neurosurgeon shall participate in at least 10 cases of aneurysms per year
 - Perioperative mortality rate for aneurysm clipping shall be documented, reviewed and compared with published outcomes.
 - For AVM, treatment shall be available including microsurgical excision, endovascular embolization and stereotactic radiosurgery
 - 8 CME credits in area directly related to cerebrovascular disease
- Acute Stroke Teams
 - Physicians with experience in diagnosing and treating cerebrovascular disease
 - Hospital based stroke team shall be available within 15 minutes by phone and at the bedside within the time period as designated by the stroke center director 24/7.
 - Response time may also be accomplished through telemedicine.
 - Evidence of stroke team log
 - Response times
 - Patient diagnosis
 - Treatments and actions
 - Outcomes
 - Documentation indicates that on a 24/7 basis, 80 percent of acute stroke patients have a diagnostic brain image completed and interpreted within 45 minutes of arrival
 - Monitoring systems
 - Heart rate / rhythm with automatic arrhythmia detection
 - Blood pressure with noninvasive BP monitoring
 - Oximetry

- Written Care Protocols
 - Written protocols/care paths for the acute workup and treatment are available in the
 - ED department
 - Acute care areas
 - Stroke units
 - Protocols include management of:
 - Ischemic stroke
 - Hemorrhagic stroke
 - tPA treatment
 - Interventional treatment (neurovascular)
- IV Thrombolytic therapy
 - The organization's formulary or medication list shall include a thrombolytic therapy (IV administered) medication for ischemic stroke
 - Documentation indicates the reason eligible ischemic stroke patients did not receive an IV thrombolytic therapy
 - Emergency department licensed independent practitioners have 24 hour access to a timely, informed consultation about the use of IV thrombolytic therapy, obtained from a physician, privileged in the diagnosis and treatment of ischemic stroke.
 - Use of the protocol, including IV thrombolytic therapy when indicated by the treating licensed independent practitioner, is reflected in the order sets or pathways, and is documented in the patient's medical record according to organizational procedure.
 - There is evidence that specific stroke performance measurement data, focused on use of IV thrombolytic therapy, are evaluated the quality improvement process and by the stroke team
- Telemedicine/telecommunication
 - Institution able to function as Hub for referral hospitals
 - Available 24/7
- Physicians who perform Carotid Endarterectomy
 - Surgeons with expertise in performing CEA's
 - Surgeons as a group shall perform a minimum number of 10 CEA's per year.
 - Results shall be audited on a yearly basis, and the results of a rolling average of at least 3 years shall be compared with published outcome and complication rates.
- Diagnostic Radiologists
 - Able to evaluate imaging studies 24/7
 - Available to read scans within 20 minutes of completion
 - Board certified/board eligible
- Neuroendovascular specialist(s)
 - Trained in neuroradiology, neurosurgery, vascular surgery, neurology, or cardiology
 - Completed neuroendovascular training that included minimum recommended standards for diagnostic angiography and neuroendovascular interventions as recommended by the major specialty societies and/or boards

- Available 24/7
- Board certified/board eligible in the specialty
- Results shall be audited on a yearly basis, and the results of a rolling average of at least 3 years shall be compared with published outcome and complication rates. Cases shall be peer reviewed as seen fit by the institution.
- ED (Emergency Department) personnel (physicians, nurses and EMS)
 - Written care protocols for acute stroke patients shall be available to EMS and ED personnel, and shall be reviewed and revised annually.
 - Annual review of EMS protocols with EMS medical director shall include
 - Rapid, efficient patient assessment and triage
 - Prehospital EMS communication with hospital staff
 - Medical stabilization en route
 - Rapid communication between EMS and ED personnel during the transportation of acute stroke patients
 - ED protocols shall include
 - Well-defined and documented procedures for calling the acute stroke team
 - Goal door to needle time of 60 minutes or less for the administration of tPA to stroke patients
 - ED care providers are familiar with
 - Pathology, presentation, assessment, diagnostics, and treatment of patients with acute stroke
 - The location and application of stroke-related protocols, activation of the acute stroke team, and communications with inbound EMS
 - The recognition, assessment and management of acute stroke complications.
 - Eighty percent of ED practitioners that provide direct patient care are knowledgeable of the pathophysiology, presentation, assessment, diagnostics, and treatment of patients with acute stroke including:
 - Initial treatment plan: treatment of the patient during the first three hours of care, including thrombolytic therapy for patients who present within three hours of initial onset of symptoms.
 - Indications for use of IV thrombolytic therapy
 - Contraindications to IV thrombolytic therapy
 - Education to be provided to patients and families regarding the risks and benefits of IV thrombolytic therapy
 - Signs and symptoms of neurological deterioration post IV thrombolytic therapy
 - ED and CSC staff shall meet with EMS to review patient care issues at least twice a year
 - At least 2 specific assessment criteria and benchmarks (quality assurance) related to acute stroke care shall be defined, measured and reviewed annually
 - ED personnel obtain 8 hours of continuing education or equivalent educational program annually that focus on acute stroke care or other Time Critical Diagnosis subject matter.
- Radiology Technologists
 - In-house CT technician 24/7
 - MRI technician available 24/7 (may take call from home as long as he/she can be at the hospital and MRI completed and interpreted within 2 hours
 - Available to perform CT scans within 25 minutes of arrival

- Available and able to perform CT angiography, CT perfusion and MRI with stroke specific sequences including perfusion as requested by stroke team
- Stroke Unit Nursing staff
 - Trained in the care of stroke patients
 - Trained in continuous cardiac and respiratory monitoring
- Dedicated Neurosciences ICU Nursing
 - The ICU nursing director or manager shall have at least 10 hours per year of CEU training (or equivalent educational activities) related to cerebrovascular disease
 - For critically ill stroke patients, the nurse to patient ratio in an ICU should be 1:1 or 1:2.
 - The ICU nursing staff shall be trained to assess neurologic function and deal with Neurocritical care:
 - Function of ventriculostomy and external ventricular drainage apparatus
 - Function and maintenance of ICP monitors
 - Treatment of ICP
 - Care of patients with ischemic stroke, intracerebral hemorrhage and subarachnoid hemorrhage
 - Care of patients after reperfusion therapy
 - Management of blood pressure with parenteral vasoactive agents in patients with central nervous system disorders
 - Management of intubated / ventilated patients
 - Detailed neurologic assessments and scales
 - ⊕ The ICU nurses receive at least 10 hours per year of CEU credit (or other educational programs) in areas related to cerebrovascular disease or Time Critical Diagnosis including but not limited to:
 - ~~Cerebral edema~~
 - ~~Aspiration pneumonia~~
 - ~~Infection~~
 - ~~Myocardial infarction~~
 - ~~DVT~~
 - Shall be familiar with standard neurologic assessments and scales, stroke protocols, care maps, ongoing research projects and new patients care techniques related to stroke.
- Stroke Coordinator – Full-time is a member of the core stroke team
 - Nurse practitioner or CNS
 - Or*
 - AANN certified registered nurse
 - Implement and coordinate the stroke program. Activities will include but are not limited to:
 - Monitor benchmarks
 - Patients and families education
 - Health care team education
- ICU Medical Director ~~Physicians with expertise in critical care or neurointensive care~~

- Board-eligible or board-certified neurologist, neurosurgeon, anesthesiologist, or an internist who has completed either a critical care fellowship or Neurocritical care fellowship.
 - Care for at least 20 patients with acute strokes per year and attend at least 4 hours per year of CME activities (or similar educational programs related to or focused on cerebrovascular disease)
 - Alternatively for those with critical care fellowship at least 25% of their patient population shall be stroke or critically ill neurological patients
- Physicians with expertise in echocardiography, carotid US, and Transcranial Doppler
 - Technicians may take call from home as long as he/she can be at the hospital within 1 hour of being paged
- Physical Medicine & Rehab physician(s) Rehabilitation services
 - Directed by a physician with board certification in physical medicine and rehabilitation or by other properly trained individuals (i.e., neurologist experienced in stroke rehabilitation)
- Rehabilitation Therapists
 - Consults for physical medicine and rehabilitation, PT, OT, and SLP shall be requested and assessment completed within 24 hours of admission if medically indicated
 - All therapists shall meet requirements for state licensure
 - At least 1 year experience in the treatment of stroke survivors
 - Physical therapists and speech language pathologists shall complete a master's degree.
 - Occupational therapists shall complete a master's degree
- Case Managers and Social Workers
 - Social Workers and Case Managers shall meet requirements for state licensure
 - At least 1 year experience in the treatment of stroke survivors
 - Social Workers shall complete a master's degree
 - Nurse Case Managers shall complete at least a bachelor's degree
 - Nurse Case Managers and Social Workers shall have adequate knowledge of inpatient rehabilitation facilities and community resources in their geographic region
- Multidisciplinary team of health care professionals with expertise or experience in stroke representing:
 - Clinical or Neuropsychology
 - Nutrition services
 - Pharmacy (including a Pharmacy Doctorate [Pharm D] with stroke expertise)
- Research
 - Shall have the professional and administrative infrastructure necessary to conduct clinical trials
 - Actively participate in ongoing clinical research
 - Actively carry out investigator initiated clinical research projects

- Education
 - Professional programs – CSC staff prepare and present at least 2 educational courses per year aimed at health care professionals within or outside of the CSC, and for Level II, II and IV designated Stroke Centers
 - Public education – CSC sponsor at least 2 public educational activities each year that focus on some aspect of stroke
 - Lectures
 - Screenings
 - Health fairs
- Stroke registry or another similar data collection tool
 - LOS
 - Treatments received
 - Discharge destination and status
 - Incidence of complications
 - Aspiration pneumonia
 - UTI
 - DVT
 - Discharge medications
- Participate in a national and/or state registry (or registries)
 - Acute stroke therapy outcomes
 - IV tPA
 - Endovascular / interventional stroke therapy
- Multidisciplinary institutional quality assurance committee shall meet on a monthly basis to monitor quality benchmarks and review complications.
 - Quality improvement
 - Correction of errors
 - Systems improvement
 - Overall care of patients
 - Documentation exists to reflect:
 - Performance measures and indicators tracked
 - Specific interventions to improve in the selected measure
 - Specific outcomes to determine success
 - Implementation period and re-evaluation
- Serve as a resource for Level II, III, and IV designated Stroke Centers.
- Diagnostic Imaging Equipment:
 - MRI
 - Available 24/7
 - If medically indicated, MRI completed within 2 hours of the test being ordered
 - Basic MRI
 - Diffusion-weighted (DWI) MRI
 - Magnetic resonance (MR) perfusion – optional
 - MR angiography (MRA)

- MR venography (MRV)
 - Catheter Angiography
 - Cerebral Angiography must be available 24/7
 - Digital Subtraction angiography (DSA)
 - CT Angiography
 - CT Angiography (CTA)
 - CT perfusion - optional
 - Extracranial Ultrasonography
 - Carotid US
 - Demonstrates acceptable proficiency using guidelines established by the Intersocietal Committee for the Accreditation of Vascular Laboratories (ICAVL) or a similar credentialing organization
 - Transcranial Doppler
 - The TCD laboratory shall track their results and seek certification from ICAVL or a similar organization
 - Transthoracic and Transesophageal Echocardiography
 - Tests of Cerebral Blood Flow and Metabolism
- Laboratory Services
 - Available 24/7 for initial stroke labs
 - CBC with platelet count
 - Coagulation studies (PT/INR)
 - Blood chemistries (CKMB and Troponin)
 - Documentation indicates the ability to complete and report lab tests in less than 45 minutes from arrival.
 - Documentation indicates the ability to perform an EKG and chest x-ray within the same time frame as laboratory testing.
 - Comprehensive hematological and hypercoagulability profile testing
- Neurovascular Interventional Treatment

Discussion: A workgroup comment was received stating, “Intra-arterial thrombolysis and mechanical clot disruption are not yet FDA approved therapies we may want to consider not including that as a requirement for a Level I stroke center. However, if the center is doing these therapies, we should leave in the requirement to be involved in a registry. When these are approved as therapies we can go back and add them in.”
- - Neuroendovascular specialist (eg, endovascular surgical neuroradiologist, neurosurgeon, neurologist or cardiologist)
 - Capability to perform neuroendovascular coiling or embolizations
 - IA thrombolysis
 - Mechanical thrombolysis
 - Carotid Angioplasty and stenting
 - Intracranial circulation angioplasty and stenting
 - Registry shall be established to track treatments, outcomes, and complications. For all the endovascular and surgical procedures performed, the number, indications, and outcomes should be recorded and available for review.

- Relationships with Other Stroke Levels
 - Have a documented relationship with Level II, III and Level IV hospitals, to provide professional education as well as to receive transferred stroke patients as needed.

Level II Primary Stroke Centers

- Requirements:
 - Meets the requirements specified by the Brain Attack Coalition's recommendations for a Primary Stroke Center
 - Meets the requirements specified for a Primary Stroke Center as specified by The Joint Commission
 - Follows the Brain Attack Coalition's benchmark treatment times:
 - Door to physician exam = 10 minutes
 - Door to Stroke Activation = 15 minutes
 - Door to CT Scan = 25 minutes
 - Door to CT Report = 45 minutes
 - Door to tPA = 60 minutes
 - Ability to implement thrombolytic treatment and transfer for complex cases to a higher level of care for complex cases
 - Hospital support for state policies to bypass hospital for a higher level when prehospital triage indicates the need for higher level of care
 - Hospital support and participation as stroke hospital in a regional Hub and Spoke system with at least one regional Hub hospital
 - Hospital and Administrative support
- Acute Stroke Teams
 - Physician with experience in diagnosing and treating cerebrovascular disease
 - Hospital based stroke teams shall be available within 15 minutes by phone and at the bedside within the time period as designated by the stroke center director 24/7.
 - Response time may also be accomplished through telemedicine.
 - Evidence of stroke team log
 - Response times
 - Patient diagnosis
 - Treatments and actions
 - Outcomes
 - Documentation indicates that on a 24/7 basis, 80 percent of acute stroke patients have a diagnostic brain image completed and interpreted within 45 minutes of arrival
 - Heart rate / rhythm with automatic arrhythmia detection
 - Blood pressure with noninvasive BP monitoring
 - Oximetry
- Written Care Protocols
 - Written protocols/care paths for the acute workup and treatment are available in the
 - ED department
 - Acute care areas
 - Stroke units
 - Protocols include management of:
 - Ischemic stroke

- Hemorrhagic stroke
 - tPA treatment
 - Interventional treatment (neurovascular)
- IV Thrombolytic therapy
 - The organization's formulary or medication list shall include a thrombolytic therapy (IV administered) medication for ischemic stroke
 - Documentation indicates the reason eligible ischemic stroke patients did not receive an IV thrombolytic therapy
 - Emergency department licensed independent practitioners have 24 hour access to a timely, informed consultation about the use of IV thrombolytic therapy, obtained from a physician, privileged in the diagnosis and treatment of ischemic stroke.
 - Use of the protocol, including IV thrombolytic therapy when indicated by the treating licensed independent practitioner, is reflected in the order sets or pathways, and is documented in the patient's medical record according to organizational procedure.
 - There is evidence that specific stroke performance measurement data, focused on use of IV thrombolytic therapy, are evaluated the quality improvement process and by the stroke team
- Emergency Medical Systems
 - Treatment guidelines for pre-hospital personnel
 - EMS protocols shall include
 - Rapid, efficient patient assessment and triage
 - Prehospital EMS communication with hospital staff
 - Medical stabilization en route
 - Rapid communication between EMS and ED personnel during the transportation of acute stroke patients
- Emergency Department
 - ED care providers are familiar with
 - Pathology, presentation, assessment, diagnostics, and treatment of patients with acute stroke
 - The location and application of stroke-related protocols, activation of the acute stroke team, and communications with inbound EMS
 - The recognition, assessment and management of acute stroke complications.
 - Eighty percent of ED practitioners must provide evidence that they are knowledgeable in the pathophysiology, presentation, assessment, diagnostics, and treatment of patients with acute stroke including:
 - Initial treatment plan: treatment of the patient during the first three hours of care, including thrombolytic therapy for patients who present within three hours of initial onset of symptoms.
 - Indications for use of IV thrombolytic therapy
 - Contraindications to IV thrombolytic therapy
 - Education to be provided to patients and families regarding the risks and benefits of IV thrombolytic therapy
 - Signs and symptoms of neurological deterioration post IV thrombolytic therapy
- Stroke Units

- Care providers demonstrate evidence of initial and ongoing training in the care of the acute stroke patient
- Stroke protocols / care paths are followed
- ~~○ Receive 8 hours CEU's (or equivalent educational activity) yearly~~
- Monitoring systems
 - Heart rate / rhythm with automatic arrhythmia detection
 - Blood pressure with noninvasive BP monitoring
 - Oximetry
- Neurologists
 - Board certified/board eligible
 - Neurologist shall be available 24/7, and response time is within 5 (20?) minutes
- Neurosurgeons
 - Board certified/board eligible
 - Neurologist shall be available 24/7, and response time is within 5 (20?) minutes
- Neurosurgical Services
 - Neurosurgical services are available within 2 hours of when it is deemed clinically necessary or has protocol for transfer to appropriate facility
 - Facilities that do not transfer patients for neurosurgical emergencies has a fully functional OR facility and staff available within 2 hours of when it is deemed clinically necessary
- Neuroimaging
 - Available 24/7
 - CT scans obtained within 25 minutes of being ordered
 - CT image evaluated by qualified personnel within 20 minutes of completion
 - Review of the images does not have to be done on site. Evaluation can be performed off site by telemedicine technology.
 - Documentation indicates that on a 24/7 basis, 80 percent of acute stroke patients have a diagnostic brain image completed within 45 minutes of it being ordered
- Laboratory Services
 - Available 24/7 for initial stroke labs
 - CBC with platelet count
 - Coagulation studies (PT/INT)
 - Blood chemistries (CKMB and Troponin)
 - Documentation indicates the ability to complete and report lab tests in less than 45 minutes from being ordered
 - Documentation indicates the ability to perform an EKG and chest x-ray within the same time frame as laboratory testing
 - Comprehensive hematological and hypercoagulability profile testing
- Outcomes / Quality Improvement
 - Evidence of specific stroke performance measurement and review by quality improvement department and stroke team.
 - Documentation exists to reflect:
 - Performance measures and indicators tracked
 - Specific interventions to improve in the selected measure

- Specific outcomes to determine success
 - Implementation period and re-evaluation
- Educational Programs
 - Minimum of one stroke public education activity per year
- Relationships with Other Stroke Level Hospitals
 - Have a documented relationship with Level III and Level IV hospitals, to provide professional education as well as to receive transferred stroke patients as needed.

Level III Support Stroke Centers

- Requirements:
 - Follows the Brain Attack Coalition's benchmark treatment times:
 - Door to physician exam = 10 minutes
 - Door to Stroke Activation = 15 minutes
 - Door to CT Scan = 25 minutes
 - Door to CT Report = 45 minutes
 - Door to tPA = 60 minutes
 - Ability to implement thrombolytic treatment and transfer to a higher level of care
 - Hospital and administrative support for state policies to bypass hospital for a higher level when prehospital triage indicates the need for higher level of care
 - Hospital support and participation as stroke hospital in a regional Hub and Spoke system with at least one regional Hub hospital
 - Established telestroke system with at least one regional Hub hospital
 - Transfer agreement in place with either Level I or Level II centers
- Acute Stroke Teams

Acute stroke team members defined by the institution

Physician or licensed independent practitioner with experience in diagnosing and treating cerebrovascular disease

 - Available within 5 minutes by phone and at the bedside within 20 minutes, 24/7.
 - Response time may also be accomplished through telemedicine.
 - Evidence of stroke team data collection
 - Response times
 - Patient diagnosis
 - Treatments and actions
 - Outcomes
- Written Care Protocols
 - Written protocols/care paths for the acute workup are available in the ED
 - Ischemic and Hemorrhagic stroke care
- tPA treatment Emergency Medical Systems
 - Treatment guidelines for pre-hospital personnel
 - EMS/first responder protocols shall include
 - Rapid, efficient patient assessment and triage
 - Prehospital EMS communication with hospital staff
 - Medical stabilization en route
 - Rapid communication between EMS and ED personnel during the transportation of acute stroke patients to a higher level of care
- Emergency Department
 - ED care providers are familiar with
 - Pathology, presentation, assessment, stroke scales, diagnostics, and treatment of patients with acute stroke

- The location and application of stroke-related protocols, activation of the acute stroke team, and communications with inbound EMS
 - The recognition, assessment and management of acute stroke complications.
- 80 percent of the ED care providers can provide evidence of review of the acute stroke protocol
- Neurosurgical Services
 - Neurosurgical services are available within 2 hours of when it is deemed clinically necessary or has protocol for transfer to appropriate facility
- Neuroimaging
 - Review of the images does not have to be done on site. Evaluation can be performed off site by telemedicine technology.
 - Documentation indicates that on a 24/7 basis, 80 percent of acute stroke patients have a diagnostic brain image completed and reviewed within 45 minutes of arrival.
- Laboratory Services
 - Available 24/7 for initial stroke labs
 - CBC with platelet count
 - Coagulation studies (PT/INR)
 - Blood chemistries (CKMB and Troponin)
 - Documentation indicates the ability to complete and report lab tests in less than 45 minutes from arrival.
 - Documentation indicates the ability to perform an EKG and chest x-ray within the same time frame as laboratory testing.
- Outcomes / Quality Improvement
 - Evidence of ongoing specific stroke performance measurement and review by quality improvement department and stroke team.
 - Documentation exists to reflect:
 - Performance measures and indicators tracked
 - Specific interventions to improve in the selected measure
 - Specific outcomes to determine success
 - Implementation period and re-evaluation
- Educational Programs
 - Minimum of one stroke public education activity per year
 - Stroke team members:
 - NIHSS certification maintained
 - tPA competency annually
 - ~~TCD education~~ 8 hours of TCD education annually
- Documented Relationships with either a Level I or Level II Stroke Center
 - Have a documented relationship with Level I and Level II hospitals, to receive professional education as well as to transfer stroke patients to those facilities as needed.

Level IV Hospitals

- Requirements:
 - These hospitals have an established relationship with a Level I, II or III hospital for management and transport of the acute stroke patient.
 - ED staff trained in recognition of stroke signs and symptoms.
 - Protocols in place for rapid identification and transport

Resources

1. Recommendations for the Establishment of Primary Stroke Centers: Mark J. Alberts, MD; George Hademenos, PhD; Richard E. Latchaw, MD; Andrew Jagoda, MD; John R. Marler, MD; Marc R. Mayberg, MD; Rodman D. Starke, MD; Harold W. Todd; Kenneth M. Viste, MD; Meighan Girgus; Tim Shephard, RN; Marian Emr; Patti Shwayder, MPA; Michael D. Walker, MD; for the Brain Attack Coalition *JAMA*. 2000;283:3102-3109.
2. Recommendations for Comprehensive Stroke Centers: A Consensus Statement From the Brain Attack Coalition. Mark J. Alberts, MD; Richard E. Latchaw, MD; Warren R. Selman, MD; Timothy Shephard, RN; Mark N. Hadley, MD; Lawrence M. Brass, MD; Walter Koroshetz, MD; John R. Marler, MD; John Booss, MD; Richard D. Zorowitz, MD; Janet B. Croft, PhD; Ellen Magnis, MBA; Diane Mulligan; Andrew Jagoda, MD; Robert O'Connor, MD; C. Michael Cawley, MD; J.J. Connors, MD; Jean A. Rose-DeRenzy, CN, RN; Marian Emr; Margo Warren; Michael D. Walker, MD for the Brain Attack Coalition. *Stroke*. 2005;36:1597.
3. The National Institute of Neurological Disorders and Stroke rt-PA Stroke Study Group. Tissue plasminogen activator for acute ischaemic stroke. *N Engl J Med*. 1995;333:1581-1587.
4. NIHSS Score and Arteriographic Findings in Acute Ischemic Stroke Urs Fischer, MD; Marcel Arnold, MD; Krassen Nedeltchev, MD; Caspar Brekenfeld, MD; Pietro Ballinari, MSc; Luca Remonda, MD; Gerhard Schroth, MD Heinrich P. Mattle, MD. *Stroke*. 2005;36:2121.
5. Endovascular Mechanical Clot Retrieval in a Broad Ischemic Stroke Cohort. D. Kima,b, R. Jahana,d, S. Starkmane, A. Aboliana, C.S. Kidwella,b, F. Vinuelaa,d, G.R. Duckwilera,d, B. Ovbiagelea,b, P.M. Vespaa,c, S. Selcoa,b, V. Rajajeea,b and J.L. Saver. *American Journal of Neuroradiology* 27:2048-2052, November-December 2006
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7. Mechanical Thrombectomy for Acute Ischemic Stroke. Final Results of the Multi MERCI Trial. Smith WS, Sung G, Saver J, Budzik R, Duckwiler G, Liebeskind DS, Lutsep HL, Rymer MM, Higashida RT, Starkman S, Gobin YP; Multi MERCI Investigators. *Stroke*. 2008 Feb 28
8. Organizing regional networks to increase acute stroke intervention. Rymer MM, Thrutchley DE; For the Stroke Team at the Mid America Brain and Stroke Institute. *Neurol Res*. 2005;27 Suppl 1:S9-16
9. Revascularization Results in the Interventional Management of Stroke II Trial. Tomsick T, Broderick J, Carrozella J, Khatri P, Hill M, Palesch Y, Khoury J; for the Interventional Management of Stroke II Investigators. *AJNR Am J Neuroradiol*. 2008 Mar;29(3):582-587.
10. King S, Khatri P, Carrozella J, Spilker J, Broderick J, Hill M, Tomsick T; IMS & IIMS II Investigators. Anterior cerebral artery emboli in combined intravenous and intra-arterial rtPA treatment of acute ischemic stroke in the IMS I and II trials. *AJNR Am J Neuroradiol*. 2007 Nov-Dec;28(10):1890-4. Epub 2007 Sep 26.
11. Khatri P, Neff J, Broderick JP, Khoury JC, Carrozzella J, Tomsick T; IMS-I Investigators. Revascularization end points in stroke interventional trials: recanalization versus reperfusion in IMS-I. *Stroke*. 2005 Nov;36(11):2400-3. Epub 2005 Oct 13.

12. Stroke. 2007;38:1655. Guidelines for the Early Management of Adults With Ischemic Stroke A Guideline From the American Heart Association/ American Stroke Association Stroke Council, Clinical Cardiology Council, Cardiovascular Radiology and Intervention Council, and the Atherosclerotic Peripheral Vascular Disease and Quality of Care Outcomes in Research Interdisciplinary Working Groups: The American Academy of Neurology affirms the value of this guideline as an educational tool for neurologists Harold P. Adams, Jr, MD, FAHA, Chair; Gregory del Zoppo, MD, FAHA, Vice Chair; Mark J. Alberts, MD, FAHA; Deepak L. Bhatt, MD; Lawrence Brass, MD, FAHA; Anthony Furlan, MD, FAHA; Robert L. Grubb, MD, FAHA; Randall T. Higashida, MD, FAHA; Edward C. Jauch, MD, FAHA; Chelsea Kidwell, MD, FAHA; Patrick D. Lyden, MD; Lewis B. Morgenstern, MD, FAHA; Adnan I. Qureshi, MD, FAHA; Robert H. Rosenwasser, MD, FAHA; Phillip A. Scott, MD, FAHA Eelco F.M. Wijdicks, MD, FAHA
13. Largest-ever Stroke Registry Confirms Safety Of Actilyse Thrombolysis Treatment For Acute Ischaemic Stroke. Wahlgren N et al. Thrombolysis with alteplase for acute ischaemic stroke in the Safe Implementation of Thrombolysis in Stroke-Monitoring Study (SITS-MOST): an observational study. Lancet 2007;369:275-82. Results from SITS-MOST (Safe Implementation of Thrombolysis in Stroke - MOnitoring STudy) published in The Lancet today confirm that routine clinical thrombolysis therapy with Actilyse® (alteplase), the first and only approved treatment for acute ischaemic stroke, is as safe and effective as previously reported in randomised controlled trials when administered within three hours of onset of a stroke.^{1,2,3} This result is borne out across a wide range of centres, from those with specialist units to those with little previous experience.
14. Review State legislative stroke center designation
 - Texas (see attached document)

Status Report
On the
Development of a Statewide Stroke Emergency Transport
Plan

To

The Honorable Rick Perry
The Honorable David Dewhurst
The Honorable Tom Craddick
Albert Hawkins, Executive Commissioner, HHS

February 2007

DRAFT

In SB330 enacted by our legislature in 2005, a strong system to treat stroke victims in a timely manner and to improve the overall treatment of stroke victims was ordered. The Governor's EMS and Trauma Advisory Council (GETAC) Stroke Committee makes the following recommendations to meet that goal.

Texas Stroke Center Designations

(A.) The Governor's EMS and Trauma Advisory Council (GETAC) Stroke Committee of the Department of State Health Services (DSHS) recommend the designation of three levels of state recognized stroke centers/facilities as follows:

Level 1: Comprehensive Stroke Centers

Level 2: Primary Stroke Centers

Level 3: Support Stroke Facilities

(B) Each center applying for state Stroke Center/Facility level designation shall meet the following criteria:

1) Level 1: Comprehensive Centers ("CSCs") will meet the requirements of a Primary Stroke Center and those specified in the Consensus Statement of Stroke on Comprehensive Stroke Centers. (Recommendations for comprehensive Stroke centers: a consensus statement from the Brain Attack Coalition. Stroke. 2005; 36(7):1597-616.)

These include, but are not limited by, the following specifications:

- a. A 24/7 stroke team capability as defined herein plus all of the requirements specified for a Primary Stroke Center
- b. Personnel with expertise to include vascular neurology, neurosurgery, neuroradiology, interventional neuroradiology/endovascular physicians, critical care specialists, advanced practice nurses, rehabilitation specialists with staff to include physical, occupational, speech, and swallowing therapists, and social workers.
- c. Advanced diagnostic imaging techniques such as magnetic resonance imaging (MRI), computerized tomography angiography (CTA), digital cerebral angiography and transesophageal echocardiography.
- d. Capability to perform surgical and interventional therapies such as stenting and angioplasty of intracranial vessels, carotid endarterectomy, aneurysm clipping and coiling, endovascular ablation of AVM's and intra-arterial reperfusion.
- e. Supporting infrastructure such as 24/7 operating room support, specialized critical care support, 24/7 interventional neuroradiology/endovascular support, and stroke registry
- f. Educational and research programs

2) Level 2: Primary Stroke Centers ("PSCs") will meet the requirements specified in "Recommendations for the Establishment of Primary Stroke Centers, JAMA 2000 June 21; 283 (23):3125-6." They will be able to deliver stroke treatment 24/7. These include, but are not limited by, the following specifications:

- a. 24 hour stroke team
- b. Written care protocols
- c. EMS agreements and services
- d. Trained ED personnel

- e. Dedicated stroke unit
- f. Neurosurgical , Neurological, and Medical Support Services
- g. Stroke Center Director that is a physician
- h. Neuroimaging services available 24 hours a day
- i. Lab services available 24 hours a day
- j. Outcomes and quality improvement plan. At a minimum this plan will incorporate the following 13 items for tracking, performance, and reporting :
 - i. Deep Vein Thrombosis prophylaxis given
 - ii. Discharged on antiplatelet/antithrombotics
 - iii. Patients with atrial fibrillation receiving anticoagulation therapy
 - iv. Tissue Plasminogen Activator (tPA) considered
 - v. Antithrombotic medication within 48 hours of hospitalization
 - vi. Lipid profile ordered during hospitalization
 - vii. Screen for dysphagia performed
 - viii. Stroke education provided
 - ix. A smoking cessation program provided or discussed
 - x. A plan for rehabilitation was considered
 - xi. The number of EMS stroke patients transported to the facility
 - xii. The number of EMS stroke patients admitted to the hospital
 - xiii. The number of stroke cases treated with intravenous (IV) or intraarterial (IA) tPA
- k. Annual stroke CE requirement
- l. Public education program

3) Level 31: Support Stroke Facilities (“SSFs”) provide timely access to stroke care but may not be able to meet all the criteria specified in the Level 1(CSCs) and Level 2 (PSCs) guidelines. They are required to:

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The designation of a Level 3 Center is defined to allow timely access to acute stroke care that would not otherwise be available such as in rural situations where transportation and access are limited and is intended to recognize those models that deliver standard of care in a quality approach utilizing methods commonly known as “drip and ship” and telemedicine approaches.

- a. Develop a plan specifying the elements of operation they do meet.
- b. Have a Level 1 or Level 2 center that agrees to collaborate with their facility and provide the supplemental resources needed to meet the criteria outlined in the Level 2 requirements that they lack.
- c. The collaboration will provide 24/7 access to a qualified health care individual.
- d. Identify in the plan where the Level 1 or Level 2 center has agreed to collaborate with and accept their stroke patients for stroke treatment therapies the SSF are not capable of providing
- e. Obtain a written agreement between the Level 1 or Level 2 Stroke Center with their facility specifying the collaboration and interactions.
- f. Develop written treatment protocols which will include at a minimum:
 - 1. Transport or communication criteria with the collaborating/accepting Level 1 or Level 2 center.
 - 2. Protocols for administering thrombolytics and other approved acute stroke treatment therapies.

- g. Obtain an EMS/RAC agreement that:
 - 1. clearly specifies transport protocols to the SSF, including a protocol for identifying and specifying any times or circumstances in which the center cannot provide stroke treatment; and,
 - 2. specifies alternate transport agreements that comply with GETAC EMS Transport protocols.
- h. Document ED personnel training in stroke.
- i. Designate a stroke director (this may be an ED physician or non-Neurologist physician)
- j. Employ the NIHSS for the evaluation of acute stroke patients administered by personnel holding current certification
- k. Clearly designate and specify the availability of neurosurgical and interventional neuroradiology/endovascular services.
- l. Document access and transport plan for any unavailable neurosurgical services within 90 minutes of identified need with collaborating Level 1 or 2 Stroke Center.
- m. Be a licensed DSHS general hospital

4) Any center applying for or receiving a state Stroke Center/Facility level designation must maintain active participation in their designated RAC.

(C) Centers or hospitals requesting Level 1, Level 2, or Level 3 state-approved Stroke Center/Facility designation will submit a signed affidavit by the CEO of the organization to the DSHS detailing compliance with the requirements designated in this Rule.

- 1.) Centers or hospitals seeking Level 1 CSC or Level 2 PSC state-approved Stroke Center designation who submit a copy of that level of certification by state-recognized organizations such as JCAHO shall be assumed to meet the requirements pursuant to this Rule.
- 2.) Each center or hospital shall submit annual proof of continued compliance by submission of a signed affidavit by the CEO of the organization.
- 3.) The DSHS may review sites as needed to verify compliance.

(D) DSHS will publish a list on its website of hospitals or centers meeting state approved criteria and their Stroke Center/Facility designation. This list will also be made available to the state RAC's for their EMS transportation plans.

- 1.) Centers holding JCAHO or other state-recognized certification will be specified with an additional qualifier and will be listed prior to listing centers holding similar level designation without formal certification.

(E) If a hospital or center fails to meet the criteria for a state Stroke Center/Facility level designation for more than 6 weeks or if a hospital or center no longer chooses to maintain state Stroke Center/Facility level designation, the hospital shall immediately notify, by certified mail return receipt requesting, the DSHS, local EMS, and governing RAC.

(F) If a hospital is in good standing and on the approved state Stroke Center list, the hospital may advertise to the public its state-approved status and state level designation. A Texas Level 1 (CSC) may use the words, "Texas-approved Level 1 Stroke Center" or "Texas-approved Comprehensive Stroke Center". A Level 2 center may use the words, "Texas-approved Level 2 Stroke Center" or "Texas-approved Primary Stroke Center". A Level 3 Stroke Facility approved

by the state may use the words “Texas-approved Level 3 Support Stroke Facility” or “Texas-approved Support Stroke Facility”. If the hospital or center is removed from state-approved level Stroke Center/Facility designation, no further public advertising is allowed and existing advertising must, where feasible, be removed from public distribution within 60 days from the date of removal. To the extent that removal of advertisement is infeasible, for example advertisement previously distributed in magazines, newspapers or on the internet, any automatic renewal of such advertisement shall be cancelled upon removal, and no further advertisement in said media shall be pursued.

Early Treatment Protocols for Rapid Transport

The Governor’s EMS and Trauma Advisory Council (GETAC) Stroke Committee of the Department of State Health Services (DSHS) recommend that the initial stroke transport plan have 3 components that each RAC should implement:

1. Appointment of a “stroke committee” to develop and oversee a region-specific stroke transport plan.
2. The regional plan will conform to the following general principles:
 - a. A written plan is developed for regional triage of stroke patients to hospitals best able to care for them.
 - b. Emergency transportation of patients out to 8 hours from symptom onset. This time window can be altered as new therapies become available.
 - c. Instruct paramedics to take patients to the highest level state designated Stroke Center if available within the region (or adjacent region, if a higher level Stroke Center in the adjacent region is closer than a lower level Stroke Center in the region). In making this determination, distance and time parameters should be considered. There should be no more than a 15 minute delay caused by taking a patient to the next highest level of stroke care. Where the available stroke care level and Stroke Centers/Facilities are comparable, a scheme should be developed to ensure a fair distribution of patients among qualified Stroke Centers/Facilities.
3. Create and maintain a registry of the number and destination of stroke patients transported and submit yearly to the DSHS.

Emergency Medical Services Training

The Governor’s EMS and Trauma Advisory Council (GETAC) Stroke Committee of the Department of State Health Services (DSHS) is cognizant that training and oversight of EMS personnel can be time and resource intensive, and so recommends the following minimal additions be added to Emergency Medical Service Provider’s licensure detailed in the Texas Administrative Code.

- 1) That all EMS providers be trained and use the “Cincinnati Stroke Scale” in the assessment of possible stroke victims.
- 2) That all certified EMS providers receive training in the recognition and emergency care of stroke, equivalent to training received in the current “ACLS Case 10 stroke scenarios”.

- 3) That EMS providers have documented familiarity with the Stroke Center Certification and the Emergency Transport Protocol in their RAC.
- 4) That recognition and documentation of stroke training be overseen by the Medical Director supervising the EMS personnel.
- 5) That current ACLS certification be recognized as documentation of that training or that alternatively the supervising Medical Director be responsible for the oversight, documentation and attestation of equivalent training on a yearly basis.

Coordination and Community Education of Stroke Plan

The GETAC Stroke Committee is cognizant that such programs can be time and resource intensive, and recommends the Department of State Health Services (DSHS) and the Texas Council on Cardiovascular Disease and Stroke perform the following:

- Develop an effective and resource-efficient plan educating cities and RACs of the new GETAC rules on stroke facilities and emergency transport plan,
- conduct health education, public awareness, and community outreach on the emergent care of stroke and its prevention,
- coordinate its activities among other agencies within the state,
- develop a database of treatment and care of stroke,
- develop a web site and information on state stroke centers and facilities,
- collect and analyze information related to stroke and the state stroke plan, and
- include stroke care as a criteria in its Recognition Programs.

NOTE: Our thank you to Debbie Summers who volunteered during the October Workgroup to research information about CEA per year by hospital. Her report is below. The December 2 Workgroup discussed.

CEA Background for discussion:

- In its first quality improvement initiative, the Leapfrog Group named CEA as one of the surgical procedures that should be performed in hospitals meeting minimum annual procedure volumes, suggesting that a hospital should perform at least 100 procedures/year in order to obtain the best outcomes. Birkmeyer JD, Finlayson EV, Birkmeyer CM. Volume standards for high-risk surgical procedures: potential benefits of the Leapfrog initiative. *Surgery*. 2001;130:415–422. [PubMed].
- Annual surgical volume for carotid endarterectomy (CEA) procedures

The number of surgeries a hospital or surgeon performs is easily measured and has been used to denote clinical expertise. Procedure volume (number of cases per surgeon) has therefore become a widely-used quality indicator for surgery.

- According to the Agency for Healthcare Research and Quality (AHRQ), a higher volume of carotid endarterectomy cases is associated with lower mortality and complication rates. Lower-volume facilities with well-trained surgeons may also achieve excellent clinical outcomes; however, the odds favor patients who are treated in hospitals with a higher number of procedures.
- Some hospitals care for patients with a greater severity of illness and their outcomes may reflect the increased surgical risk of those patients, e.g., sicker patients may increase the likelihood of poor outcomes.
- Individual surgeon volume for carotid endarterectomy (CEA)
- It has been suggested that the volume of procedures performed by an individual surgeon, rather than the hospital as a whole, has more bearing on the outcomes of carotid endarterectomy (CEA) procedures. (*Journal of the American College of Surgeons*, December 2002: 195(6); 814-821)
- While there has been no guideline set for the number of carotid endarterectomies (CEA) a surgeon should perform to maintain quality, studies suggest that 10-50 procedures/year should be performed to maintain competence. (*American Journal of Surgery*, May 2001: 181(5); 450-453)
- The Leapfrog Volume Criteria May Fall Short in Identifying High-Quality Surgical Centers.
- Original Papers and Discussions
- *Annals of Surgery*. 238(4):447-457, October 2003.
*Christian, Caprice K. MD, MPH **; *Gustafson, Michael L. MD, MBA **; *Betensky, Rebecca A. PhD +*; *Daley, Jennifer MD ++*; *Zinner, Michael J. MD **
- Abstract:
Objective: The original Leapfrog Initiative recommends selective referral based on

procedural volume thresholds (500 coronary artery bypass graft [CABG] surgeries, 30 abdominal aortic aneurysm [AAA] repairs, 100 carotid endarterectomies [CEA], and 7 esophagectomies annually). We tested the volume-mortality relationship for these procedures in the University HealthSystem Consortium (UHC) Clinical DatabaseSM, a database of all payor discharge abstracts from UHC academic medical center members and affiliates. We determined whether the Leapfrog thresholds represent the optimal cutoffs to discriminate between high- and low-mortality hospitals.

- Methods: Logistic regression was used to test whether volume was a significant predictor of mortality. Volume was analyzed in 3 different ways: as a continuous variable, a dichotomous variable (above and below the Leapfrog threshold), and a categorical variable. We examined all possible thresholds for volume and observed the optimal thresholds at which the odds ratio is the highest, representing the greatest difference in odds of death between the 2 groups of hospitals.
- Results: In multivariate analysis, a relationship between volume and mortality exists for AAA in all 3 models. For CABG, there is a strong relationship when volume is tested as a dichotomous or categorical variable. For CEA and esophagectomy, we were unable to identify a consistent relationship between volume and outcome. We identified empirical thresholds of 250 CABG, 15 AAA, and 22 esophagectomies, but were unable to find a meaningful threshold for CEA.
- Conclusions: In this group of academic medical centers and their affiliated hospitals, we demonstrated a significant relationship between volume and mortality for CABG and AAA but not for CEA and esophagectomy, based on the Leapfrog thresholds. We described a new methodology to identify optimal data-based volume thresholds that may serve as a more rational basis for selective referral.